

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3841. Misbranding of pentobarbital sodium capsules, sulfathiazole tablets, and penicillin tablets, and conspiracy to violate the laws of the United States. U. S. v. L. Samuel Kilbee (Imperial Pharmacy), John S. Bernreuter, Irvin M. Seay, and Roosevelt F. Mills. Pleas of nolo contendere by L. Samuel Kilbee, John S. Bernreuter, and Irvin M. Seay, and plea of not guilty by Roosevelt F. Mills. L. Samuel Kilbee fined \$500 and John S. Bernreuter and Irvin M. Seay each fined \$100. Roosevelt F. Mills tried to a jury; verdict of guilty on 2 counts charging aiding and abetting violation of Section 301 (k) and verdict of not guilty on 1 count charging conspiracy to violate the laws of the United States; fine, \$300. (F. D. C. No. 30020. Sample Nos. 1150-K, 1152-K, 1156-K, 1255-K, 1586-K.)

INFORMATION FILED: May 3, 1951, Southern District of Florida, against L. Samuel Kilbee, trading as the Imperial Pharmacy, at Jacksonville, Fla., John S. Bernreuter and Irvin M. Seay, pharmacists employed by the Imperial Pharmacy, and Roosevelt F. Mills, a physician.

INTERSTATE SHIPMENT: From the States of Georgia and New Jersey into the State of Florida, of quantities of *pentobarbital sodium capsules, sulfathiazole tablets, and penicillin tablets*.

ALLEGED VIOLATION: On or about March 28 and 31, April 8, and June 16 and 21, 1949, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded. L. Samuel Kilbee was included as a defendant in each of the five counts involving sale of the drugs, and John S. Bernreuter was joined in four of such counts and Irvin M. Seay in one of such counts, and charged with the violations involved in those counts.

The information charged further that prior to the sales of the *sulfathiazole tablets* and the *penicillin tablets* (counts 4 and 5), Roosevelt F. Mills, a physician, furnished to L. Samuel Kilbee, at the Imperial Pharmacy, physician's prescription forms, which bore the signature in ink of Roosevelt F. Mills, and also the following printed matter: "Reg. No. 7243 Dr. R. F. Mills Physician and Surgeon 600 W. Ashley, Corner Broad Jacksonville, Fla. Office Hours: 10-2 & 6-8:30 P. M. Phones: Office 4-2244 Residence 4-2498 Patient's Name _____ Date _____ Address _____ Imperial Pharmacy Cor. Broad And Ashley Sts. Jacksonville Florida Phone 4-2159";

That the forms were furnished by Roosevelt F. Mills for the purpose of L. Samuel Kilbee filling out such forms and causing them to be filled out, and dispensing and causing drugs to be dispensed under such forms;

That John S. Bernreuter at the time of the sale involved in count 4 filled in one of the forms with the following: "William J. Barber 6/21/49 Post Office Box 711 Tablets Sulfathiazole 7.7 Gr. Sig. Two Tablets every 4 hours 398614 2.50 J. S. B." and dispensed the tablets in a vial labeled in part: "Imperial Pharmacy * * * #398614 Dr. Mills William J. Barber Two Tablets Every four hours 6/21/49 J. S. B.";

That Irvin M. Seay at the time of the sale involved in count 5 filled in one of the forms with the following: "Oscar Hartley 6/16/49 Penicillin Tabs 50,000 U #12 Sig Tab ii q 4 h. 398588 \$3.50" and dispensed the tablets

in a box labeled, in part, "Imperial Pharmacy * * * 398588 Dr. Mills Two every 4 hours 6/16/49";

That the act of Roosevelt F. Mills in furnishing the prescription forms signed by him for the purposes stated above, aided and abetted L. Samuel Kilbee, John S. Bernreuter, and Irvin M. Seay in their violations of Section 301 (k).

The information alleged further, in count 6, that Roosevelt F. Mills, L. Samuel Kilbee, John S. Bernreuter, and Irvin M. Seay, combined, conspired, confederated, and agreed, together and with each other, to violate Section 301 (k) of the Federal Food, Drug, and Cosmetic Act;

That it was a part of the conspiracy that the defendants would dispense and cause to be dispensed, without labeling bearing adequate directions for use, *sulfathiazole tablets* and *penicillin tablets* which had been shipped in interstate commerce into the State of Florida and were being held for sale after such shipment;

That in pursuance of the conspiracy, at a time prior to the sales alleged in counts 4 and 5, Roosevelt F. Mills furnished to L. Samuel Kilbee, at the Imperial Pharmacy, Jacksonville, Fla., a number of physician's prescription forms hereinbefore described;

That in further pursuance of the conspiracy, and to effect the objects thereof, L. Samuel Kilbee, Irvin M. Seay, and John S. Bernreuter filled out and caused to be filled out the prescription forms for *sulfathiazole tablets* and *penicillin tablets*, respectively, hereinbefore referred to.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged *pentobarbital sodium capsules* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents. Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (f) (1), the repackaged *pentobarbital sodium capsules* failed to bear labeling containing adequate directions for use.

Misbranding, Section 502 (b) (2), the repackaged *sulfathiazole tablets* and *penicillin tablets* failed to bear labels containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the former failed to bear a label containing the common or usual name of the drug; Section 502 (e) (2), the latter failed to bear a label containing the common or usual names of each active ingredient of the drug; and, Section 502 (f) (1), both failed to bear labeling containing adequate directions for use. Further misbranding, Section 502 (f) (2), the labeling of the repackaged *sulfathiazole tablets* bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: February 8, 1952. A plea of nolo contendere having been entered by L. Samuel Kilbee, the court found him guilty on all counts and fined him \$500. Pleas of nolo contendere having been entered by John S. Bernreuter and Irvin M. Seay, the court found the former guilty on counts 1, 2, 3, 4, and 6 and the latter guilty on counts 5 and 6, and imposed fines of \$100 against each.

A plea of not guilty having been entered by Roosevelt F. Mills, he was tried to a jury on February 7 and 8, 1952. At the conclusion of the trial, the court delivered the following charge to the jury:

The COURT. "Now, Mrs. Candito and Gentlemen:

"You have heard the testimony in this case and the argument of counsel, both for the United States and for the defendant. It becomes, then, the duty of the Court to instruct you as to the law applicable to the case. You are tired, I am tired, I guess we are all tired, and I say that, because I don't want you to let that interfere with your giving careful attention to what I have to say and giving careful consideration to the verdict in this case. It is important to the government and it is important to the defendant.

"The defendant in this case, as you know, has entered a plea of not guilty to the three counts of this information which concern him, Count Four, Five and Six. The effect of that plea of not guilty is to deny every material allegation in the information, or those counts of it, and put on the government the burden of proving his guilt beyond and to the exclusion of a reasonable doubt. If the government has failed as to those three counts, or any one of them, to prove the material allegations thereof beyond and to the exclusion of every reasonable doubt, then it is your duty to acquit the defendant, or to acquit him as to such counts as you find the government has failed to make proof beyond a reasonable doubt concerning.

"A reasonable doubt is a doubt naturally arising from the evidence, or lack of evidence. As the words import, it is a doubt conforming to reason, a doubt for which you can give a reason, or a doubt which a reasonable man would entertain. A reasonable doubt is that state or condition of the case which, after a full and fair consideration and comparison of all the evidence, leaves your mind in such condition that you cannot say that you feel an abiding conviction to a moral certainty of the truth of the charge.

"The defendant in this case, as in all criminal cases, is presumed to be innocent. This presumption of innocence accompanies the defendant and abides with him through every stage of the trial as to every material allegation of the indictment; and until your minds are convinced by the evidence beyond and to the exclusion of every reasonable doubt that he is guilty of the offense charged against him. But when your minds aren't so convinced of the guilt of the accused beyond and to the exclusion of every reasonable doubt, then that presumption of innocence ceases.

"It is on the evidence, and that alone, that you are to try the defendant. You, as jurors, under your oaths are carefully, calmly, fairly, and dispassionately to consider all the evidence in the case; and from such evidence and the law as given to you by the Court, you are to arrive at your verdict. It is your province and yours alone to pass on the disputed issues of fact in the case. It is the Court's province to give you the law in charge which you are to apply to the facts as you find them.

"You are not to be swayed from the performance of this duty by prejudice, sympathy, or any other sentiments, but you must try the case fairly and impartially on the evidence—and I emphasize that you are the sole judges of the evidence; and anything I may have to say to you by way of comment on the evidence is advisory only. The responsibility is yours to decide the question of fact involved here. I might further caution you that you are not to understand or infer from any ruling that I may have made in the course of the trial with regard to the evidence, anything I may have had to say to counsel for either side regarding the admissibility of evidence, or in ruling in any way in the case, you are not to understand any of those as being a personal opinion on my part as to the guilt or innocence of the defendant. That is just matter arising in the administration of the trial.

"You are the judges of the evidence, the weight of the evidence, and the credibility of the witnesses who have testified before you. If there is a conflict in the testimony before you, you must reconcile it, if you can, so as to make all the witnesses speak the truth, but if you cannot reconcile such a conflict, you may believe or disbelieve any witness or witnesses that you may or may not consider them entitled to credit, and if you disbelieve any witnesses, you have the right to ignore his or her testimony in making up your verdict,

although you should not captiously or capriciously disregard the testimony of any witness.

"In weighing the testimony of any witness, you should consider his apparent intelligence or want of intelligence, his relationship to the parties in the case, his interest, if any, in the result of the case, his bias or prejudice, if any, for or against the parties in the case, his appearance on the witness stand and his manner of testifying, his apparent frankness and candor, or want of frankness and candor in testifying, the reasonableness or unreasonableness of his testimony, the circumstances surrounding the witness at the time concerning which he testified, and the means and opportunity of his knowing the facts about which he testified, and all the other evidence in the case tending to corroborate or to contradict his testimony.

"In considering or weighing the evidence in this case, you should use the same judgment, reason, common sense, and general knowledge of men and affairs that you use in your everyday business life.

"Now, the defendant in a criminal case has the right to take the stand and testify in his own behalf. If and when he does so, his testimony goes to you the same as the testimony of any other witness in the case, and is to be weighed and considered by you according to the same rules—that is, the rules we have just been going over.

"Now, as to the allegations of the Fourth, Fifth, and Sixth Counts of this information which we are concerned with here, I may say that the stipulation which was read to you in the beginning takes away the necessity of proof of a good deal of those matters. It was stipulated that the drugs were shipped in Interstate commerce, that they were delivered to the Imperial Pharmacy, that they were in the containers as shown on those photostats, and that the containers were labeled as is shown, and that the labels were similar to the photostats. That is the first one, the one with the sulfathiazole, and the other one potassium G. penicillin, or penicillin potassium G—whatever it was. You remember that. There is no dispute about the drugs being in interstate commerce. Don't give yourselves any concern over that, because it is the law that they are in interstate commerce until they reach the ultimate consumer. In other words, if they came from some drug house in New York, from there to the Imperial Pharmacy, and from there to the person or persons who consumed it, all the time they were in interstate commerce, so that consideration is out of the case; you don't need to consider it. That is as to all counts of this.

"Now, going on down into the Fourth Count, that is the Count as to the sulfathiazole, which alleges that the defendant Mills aided and abetted the misbranding of this drug by furnishing the blank forms, the blank signed prescription forms to Kilbee, to the former defendant Kilbee, for the purpose of Kilbee filling them out or causing them to be filled out, and dispensing, or causing to be dispensed drugs under the prescription form.

"The next important allegation of this Fourth Count is that Bernreuter on June 21, 1949, or at some date—you don't have to be concerned with the exact date, as I think I have had occasion to charge most of you before, if the date is within three years prior to the filing of the information; so all the dates here are within the time. At any rate, Bernreuter admitted this sale to Barber, and filled in the blank form that had been previously furnished by Dr. Mills, and that this act of removal, repacking and disposal of these tablets resulted in their being misbranded within the meaning of Section 352 B of the Food and Drug Act; 21 US Code 352.

"Now, very nearly the same charge is made in the Fifth Count with respect to penicillin being sold to Oscar Hartley, by Irvin M. Seay, and that it was done by filling in this blank prescription form which has previously been furnished to Kilbee by Mills.

"The law requires that the labeling of a drug must bear adequate directions for use, otherwise it is misbranded, and that is the charge here: That it is misbranded. Now, regulations adopted having all the force and effect of law, exempt drugs from bearing on their label adequate directions for use if the drug bears the label, 'Caution: To be dispensed only by or on the prescription of a physician.' These same regulations provide that these exemptions shall expire—in other words, as if no exemptions existed, unless it bears 'Caution: To be only dispensed by a physician or by a physician's prescription.'

"Now, there is no dispute under the stipulation as to the label that the—both drugs involved here, sulfathiazole and penicillin, were received by the Imperial

Pharmacy, when they were received, both as was stated. The evidence also stated that these drugs, when sold by the Imperial Pharmacy—that is, one sold to Barber, in the Fourth Count, and the penicillin in the Fifth Count, sold to Barber in the Fifth Count, bear the instruction, “two every four hours.” Standing alone, such instructions for use of those drugs do not constitute adequate directions for use. However, if you find—and this is a matter that you have got to decide—if you find that the drugs were sold in response to valid and legitimate prescriptions of the doctor, then the drugs would bear adequate directions for use. If you find, on the other side, that the drugs were sold by the Imperial Pharmacy without valid and lawful prescription, then you must find that the drugs were misbranded at the time of the sale.

“Now, I further instruct you that a valid prescription—you will recall the testimony of Dr. Husa as to what a valid prescription was—that a valid prescription means directions to a druggist by a doctor for a particular medicine to be put up for a patient to be used at a particular time and in a particular way—the furnishing of the blank sheet of paper on a prescription form with the doctor’s signature on it is not a valid prescription, it couldn’t be; and, therefore, as to this Fourth and Fifth Count—if the drugs were sold without any contact between the doctor and the patient, to just walk in and buy them, as testified here, and it is up to you to decide whether that testimony is true—just walk in and buy them, and no connection between the doctor and the patient, and the prescription form to be filled in later, why, then, it wasn’t sold on a valid prescription.

“Now, if it was sold, if it was dispensed by the druggist after telephone conversation with the doctor, and the doctor told the druggist to dispense the drugs, it is my view that that is a valid prescription, that there can be a valid dispensing on a valid prescription by the doctor telling the druggist to give the patient so and so, without anything further. So it is up to you to decide as to those Fourth and Fifth Counts, what actually happened, how the drugs were dispensed, and whether it was by instructions of the doctor over the phone, or whether it was simply by the druggist filling in these blank prescriptions. Now, if it was done in the latter way, which you must find, as I told you, beyond a reasonable doubt, before you would be warranted in convicting under the Fourth and Fifth Counts—if it was done in that way, then the druggist that dispensed it would be guilty of misbranding by not having sold on a valid prescription, and misbranding these drugs; and the United States statutes provide that ‘whoever commits an offense against the United States or aids and abets, compels, commands, induces or procures its commission, is punishable as a principal.’

“Now, as to these Fourth and Fifth Counts, if you reach that point in your deliberations that you believe that these acts—that the druggist Seay, in one instance, and Bernreuter in the other, is guilty of selling these misbranded drugs, if you reach that point in your deliberations, you are required to determine whether or not the defendant here Mills, is guilty of aiding and abetting, since, as I just read, the statute provides that whoever aids and abets the commission of an offense is guilty as a principal. Specifically, did he aid and abet the dispensing of misbranded drugs by furnishing these blank prescriptions which I have told you wouldn’t be any prescriptions at all. If he furnished those, so that the other men could sign them—and it is up to you to decide it, whether the government has proved it beyond and to the exclusion of every reasonable doubt from all the evidence—if he did, you can find the doctor guilty under the Fourth Count or Fifth Count or both, whichever you find that that proof has been made to.

“I think that that, perhaps, is sufficient discussion of those two Counts. To come down to the next Count, which charges a conspiracy between Mills, Roosevelt Mills, the physician, the owner of the drugstore, the operator of the drugstore, and Bernreuter and Seay, the two pharmacists, that they conspired to commit offenses against the United States; that is, violate the statute about misbranding drugs. Now, as far as proving the other two Counts, intent is not an element there; that is to say, if the doctor did actually aid or abet in the commission of the offenses by the druggists, as charged there in Four and Five, his intent is not material. However, in this conspiracy charge, this intent does come into it. The charge here is: That this conspiracy existed, and that it was to dispense or cause to be dispensed without labeling bearing adequate directions for the use, drugs misbranded in viola-

tion of the statute, the penicillin tablets and sulfathiazole tablets, and it is charged that the sale to Barber—no, the first overt act charged is the furnishing,—in the carrying out of the conspiracy, the charge of furnishing of blank forms of prescriptions signed by Mills and furnished by Mills to Kilbee. Then the second overt act charged is the Hartley sale, and the third overt act charged is the Barber sale.

"Now, if two or more persons conspire to commit an offense against the United States, and one or more of such conspirators do an act to effect the object of the conspiracy, each of the parties to the conspiracy shall be punished and so on. That is the statute under which conspiracy is charged. Conspiracy is the combination of two or more persons to accomplish by the united or concerted action a criminal or unlawful purpose, or to accomplish some lawful purpose by a criminal or unlawful means. The unlawful purpose charged here is the violation of these misbranding statutes in the regulations. When two or more persons agree together to do an unlawful act, when they combine to accomplish that by their united actions, a conspiracy is formed. It is formed when such a combination is entered into, and the offense is consummated when one or more of the parties to the conspiracy commit one or more of the overt acts charged in the indictment. It is not necessary that two or more persons meet together and enter into any explicit or formal agreement to form an unlawful scheme, to constitute a conspiracy; nor is it necessary that they should directly by words or in writing state what the unlawful scheme should be, nor detail the plans by which the unlawful scheme or combination should be effected. It is sufficient that two or more, in any amount or through any contrivance—that is, by a direct, implied, or inferred agreement amongst themselves—come to a mental understanding to accomplish a definite unlawful design. In other words, when an unlawful end is sought to be accomplished, and they work together in any way in the furtherance of the unlawful scheme, every one of such persons becomes a member of such conspiracy, although the part he is to take therein is a subordinate one, and is to be executed at a remote distance from the other conspirators. Proof of a definite plan or formal agreement by the conspirators can seldom be shown by direct evidence, and such proof is not necessary. It is as competent to prove an alleged conspiracy by circumstantial as by direct evidence. Indeed, the existence of a conspiracy is generally shown by circumstantial evidence, because an unlawful agreement or combination usually exists only in the minds of the conspirators, and such a mental state is not usually susceptible of direct proof, but must be gathered from circumstances shown in evidence. In order to establish proof of conspiracy, the circumstantial evidence, according to the facts and circumstances shown in evidence, must not only be consistent with guilt, but must be inconsistent with any other reasonable or rational hypothesis of innocence.

"While circumstantial evidence is equally available as direct evidence to prove the existence of conspiracy, mere suspicion or conjecture cannot take the place of evidence. Suspicion alone may not take the place of proof of guilt. If the facts and circumstances are as consistent with innocence as guilt, no conviction can properly be had.

"Of course, you may and should consider all the direct evidence along with the circumstantial evidence, and weigh it all together.

"Now, the conspiracy must be proven to exist beyond a reasonable doubt, and must be in existence at or prior to the commission of an overt act. If you find proof merely of an alleged overt act, without proof beyond a reasonable doubt of the conspiracy, then you should acquit this defendant as to the conspiracy count, the Sixth Count.

"And you further understand that before a conviction can be had of conspiracy, there must not only be this conspiring together that we have been talking about, but the formation of the conspiracy must be followed by the commission of one or more of the overt acts charged in the indictment, then, to effect the object of a conspiracy; for, otherwise, the conspiracy charged in the conspiracy count cannot be carried out. The overt acts need not be necessarily committed by this particular defendant. If you find that the government has proved the commission of one or more overt acts by other parties to the conspiracy in furtherance of the conspiracy—that is, one or more of the overt acts charged in the indictment. In other words, if the conspiracy was formed, then at the moment that the overt acts, or any one of

them were done to effect the continued existence of the conspiracy, and to effect the object of the conspiracy, at that moment, criminal responsibility for the intents charged in this Sixth Count was consummated, by these acts or any of them done to effect the object of the conspiracy. Though certain acts were done by only one party this would bind each and every party to the conspiracy, and such act becomes the act of every party to the conspiracy.

"Now, evidence of the defendant's good character should be considered by you with the other evidence in the case, and may, in connection therewith, be sufficient to raise a reasonable doubt in your minds as to the defendant's guilt. Evidence of the defendant's good character is of the same category as other factual evidence, and must be considered by you in your deliberations, and may of itself be believed by you and create a reasonable doubt, where heretofore no reasonable doubt would exist.

"The defendants in this case, other than Dr. Mills, have pleaded nolo contendere, therefore are not being tried by you along with the defendant Mills. You are not to permit the fact that the other defendants have entered such a plea to have any connection; you are to consider only the charges for which he is now being tried before you.

"Now, I think that that is a sufficient discussion for the purposes of the evidence here. You are to weigh all the circumstances in evidence as to each count of the indictment—or the information—as you find it as they may apply, and reach a unanimous verdict. You understand all twelve of you must concur, and reach a unanimous verdict as to the guilt or innocence of the defendant. If you find he is guilty—after consideration and comparison of all of the evidence, if you find that the government has made out a case beyond and to the exclusion of a reasonable doubt as to one or more counts of the indictment—or the information—you say in your verdict: 'We, the Jury, find the defendant Roosevelt Mills guilty of the charge in count blank,' and specify which count of which you find him guilty.

"If the government has failed in its proof of any one or more of the counts of the information beyond a reasonable doubt, you find him not guilty, and you say in your verdict, 'We, the Jury, find the defendant Roosevelt Mills not guilty, so say we all.' And, as I say, your verdict must be unanimous. One of you must sign it as foreman, dated Jacksonville, Florida. You should select a foreman when you first go out, and let the foreman preside over your deliberations and sign the verdict.

"Are there any further objections, other than the objections in chambers, as to the charge?

"Are there any further objections you want to make?"

Mr. WALKER. "No, Your Honor."

Mr. ROTHSTEIN. "No, Your Honor."

The COURT. "Now, you are not concerned with the first three counts of this indictment. There's only four, five, and six——— it is an information; I keep calling that thing an indictment; it is an information signed by the United States Attorney. Take that, and the exhibits in.

"You may retire, then, for consideration of your verdict."

The jury having found the defendant, Roosevelt F. Mills, guilty on counts 4 and 5 involving the charge of aiding and abetting in the illegal sale of *sulfathiazole tablets* and *penicillin tablets* and not guilty on count 6 involving the charge of conspiracy to violate the laws of the United States, the court imposed a fine of \$300.

3842. Misbranding of Seconal Sodium capsules. U. S. v. Frank C. Tuma (Tuma Drugs). Motions for dismissal of information and for bill of particulars denied. Plea of guilty. Fine of \$300, plus costs. (F. D. C. No. 28104. Sample Nos. 42113-K to 42115-K, incl.)

INFORMATION FILED: January 17, 1950, Northern District of Illinois, against Frank C. Tuma, trading as Tuma Drugs, at Oak Park, Ill.

ALLEGED VIOLATION: On or about February 10, 14, and 23, 1949, while a number of *Seconal Sodium capsules* were being held for sale at Tuma Drugs after shipment in interstate commerce, the defendant caused a number of such